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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,576	08/11/2005	Robert James Nash	133604-00101	3120

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
08/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,576	NASH ET AL.	
	Examiner	Art Unit	
	TIFFANY M. GOUGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *10-19 and 21-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/2010 has been entered.

The previous rejection of claim 1 and dependent claims 2-9 under 35 U.S.C. 112, first paragraph is ***withdrawn*** in light of applicants claim amendments filed 7/23/2010.

Claims 1-38 are pending. Claims 10-19, 21-38 are withdrawn. Claims 1-9, 20 have been considered on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and dependent claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step which correlates the characterizing to the quality of an herbal medicine. As currently claimed, there is no step which the quality is actually monitored and how the characterizing step relates to the quality of the drug.

Response to Arguments

Applicant's arguments filed 7/23/2010 have been fully considered but they are not persuasive. Applicant argues that one skilled in the art would be familiar with and utilize the method to determine quality of the herbal medicine. Thus, specific steps required to correlate the quality of medicine from the characterization step is not essential to the invention.

Applicants argument has been considered however, it is important to note that applicant argues that the Elbein reference does not teach a step of quality monitoring. Applicant cites their specification to define what "quality" means with regards to the instant invention. Applicant defines quality monitoring to include identifying the presence of a bioactive principle or marker. Therefore, without a specific step in which the quality is actually monitored and how the characterizing step relates to the quality of the drug, applicants arguments regarding Elbein are problematic. As claimed, Elbein anticipates the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Elbein (5021427).

Applicant claims a method comprising providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of polar phytochemicals and a non-polar residue and characterizing the phytochemical. Applicants claim the extract to be fractionated prior to characterization. Applicants claim fractionation by ion-exchange chromatography and gas-liquid chromatography (GLC) and derivitization prior to GLC.

Elbein teaches extracting seed material with methanol to produce a polar phytochemical, specifically pyrrolizidine alkaloids, purifying the extract with ion-exchange chromatography and fractionating the product by TLC and GC with derivitization (col. 9, lines 59-31, esp. col. 9, lines 59-68, col. 10, lines 8-12 and 28-31). Elbein teaches characterizing the extract (col.9-11).

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of WO 99/34810, Abidi (Journal of Chromatography, 2001) and Khwaja et al. (US 6113907) in view of Elbein (US 5021427) supported by Karuza et al. (J. of Pharm and Biomed. Analysis, 1996).

Applicant claims a method comprising providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of polar phytochemicals and a non-polar residue and characterizing the phytochemical. Applicants claim the extract to be fractionated prior to characterization. Applicants claim fractionation by ion-exchange chromatography and gas-liquid chromatography (GLC) and derivitization prior to GLC.

WO 99/34810 teaches a method comprising providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of phytochemicals and a non-polar residue and characterizing the phytochemical. WO 810' teach the extract to be fractionated prior to characterization. WO '813 teach fractionation by chromatography methods, scavenging of non-ionic residues by subjecting the residue to hydrophobic interaction (HIC) and/or reverse-phase chromatography (RPC) and fractionation of the scavenged extract by HPLC (p.7-10, p. 11-45).

Abidi teaches extraction, fractionation, derivitization and chromatography methods used for the analysis of plant extracts. Abidi teaches providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of phytochemicals and a non-polar residue and characterizing the phytochemical. Abidi teach the extract to be fractionated prior to characterization. Abidi teach fractionation by chromatography methods, scavenging of non-ionic residues by subjecting the residue to hydrophobic interaction (HIC) and/or reverse-phase chromatography (RPC) and fractionation of the scavenged extract by HPLC (p.176-198).

Khwaja teach a method for monitoring a herbal medicine comprising providing a sample of an herbal medicine, extracting with polar solvents to produce polar phytochemicals including alkaloids and characterizing the extraction (col. 2,lines 40-51, col. 3, lines 23-27, 47-58, col. 9, lines 1-20, col. 10, lines 10-15, 58-60, col. 12, lines 60-65). They further teach fractionation by various known methods in the art such as chromatography methods including, GC, HPLC, RPC as well as scavenging by RPC (col. 11, lines 50-55, col. 14, lines 64-67, col. 17, lines 10-33, col. 18, lines 5-10, col. 19, lines 40-45, col. 20, lines 5-18, 59-60, col. 22, lines 30-36). They teach that the characterizing is important in determining quality for use as a pharmaceutical grade product and for insuring quality of the drug consistent with use as human or veterinary prophylactic or therapeutic agents (col. 12, lines 25-36).

The above references do not teach the polar phytochemicals pyrrolidine, piperidine, pyrrolizidine, indolizidine, tropane and nortropane alkaloids.

Elbein teaches extracting seed material with methanol to produce a polar phytochemical, specifically pyrrolizidine alkaloids, purifying the extract with ion-exchange chromatography and fractionating the product by TLC and GC with derivitization (col. 9, lines 59-31, esp. col. 9, lines 59-68, col. 10, lines 8-12 and 28-31). Elbein teaches characterizing the extract (col.9-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to extract of naturally-occurring plant constituents because the extraction methods taught by the references can be used to extract polar phytochemicals such as those claimed. Further, the claimed methods for extracting, fractionating and characterizing the claimed phytochemicals are all routine in the art for the claimed purpose, i.e. extraction, fractionation and characterization of plant materials, thus, the method would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the claimed invention. Nevertheless, Elbein teaches extracting seed material with methanol to produce a polar phytochemical, specifically pyrrolizidine alkaloids, purifying the extract with ion-exchange chromatography and fractionating the product by TLC and GC with derivitization (col. 9, lines 59-31, esp. col. 9, lines 59-68, col. 10, lines 8-12 and 28-31). Elbein teaches characterizing the extract (col.9-11).

Karuza is relied upon for the teachings of analyzing the quality and extracts of herbal medicines using chromatography methods.

Response to Arguments

Applicant's arguments filed 7/23/2010 have been fully considered but they are not persuasive.

In response to the Elbein reference, applicant argues that Elbein fails to disclose an "herbal medicine" as defined by applicant. Applicant argues that Elbein fails to disclose a "pharmaceutical composition." Pharmaceutical compositions are known in the art to be a chemical substance intended for use in the medical diagnosis, cure, treatment or prevention of disease. Therefore, applicants definition of pharmaceutical composition/herbal medicine is interpreted as a chemical substance/phytochemical of a plant, i.e. including extracts from a plant. Applicant argues that Elbein does not disclose any "fitness of the herbal medicament for its intended use."

It is the Examiners position that Elbein teach extracting polar phytochemicals, i.e. pyrrolizidine alkaloids, from a plant, which are known to inhibit viral or retroviral proliferation in a host. i.e inhibit HIV replication, and reduce tumor growth in a host (col. 1, lines 29-36, col. 2, lines 60-68). They teach that the bioactive alkaloid is used as a therapeutic agent to inhibit proliferation of a viral or retroviral. It is the Examiners position that Elbein clearly discloses an "herbal medicine" as defined by applicant and that Elbein does explicitly show "fitness of the herbal medicament for its intended use." Regardless, applicants invention is only drawn to an extraction and characterizing method comprising extracting a polar phytochemical and fractionating using chromatography methods. Such methods are known in the art to be useful in extracting polar and non-polar extracts.

In response to Claims 1-9, 20 rejected under 35 U.S.C. 103(a), applicant argues that the primary refernces teach non-polar phytochemicals and therefore the reference teach away from the claimed invention.

It is the Examiners position that, regardless of polar or non-polar extracts, the claimed extraction and fractionation steps/methods are well known in the art for their claimed purpose. The references teach characterizing the extracts from plant materials. The claimed methods for extracting, fractionating and characterizing the claimed phytochemicals are all routine in the art for the claimed purpose, i.e. extraction, fractionation and characterization of plant materials, thus, the method would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
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/Tiffany M Gough/
Examiner, Art Unit 1657